

**Amendment #1**  
**RFP NIH-NIAMS-02-03**  
**CLINICAL CENTERS FOR THE OSTEOARTHRITIS INITIATIVE**

Amendment to Solicitation No.: [NIH-NIAMS-02-03](#)

Amendment No.: 1

Amendment Date: September 18, 2001

RFP Issue Date: August 8, 2001

Issued By: Chief Contracting Officer  
Contracts Management Branch  
National Institute of Arthritis and Musculoskeletal  
and Skin Diseases, National Institutes of Health  
Natcher Building, Room 5AS13A  
45 Center Drive, MSC 6500  
Bethesda, MD 20892-6500

Point of Contact: [Eileen Webster-Cissel](#)

Name and Address of Contractor: N/A

The above numbered solicitation is amended as set forth below.

The hour and the date specified for receipt of offers IS NOT EXTENDED. Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

1. By requesting a copy of the Standard Form 30 for this amendment and completing the information requested in items 8 and 15, and returning 1 copy of the amendment; (a hard copy of this amendment, including the Standard Form 30, may be requested from Ms. Eileen Webster-Cissel).
2. By acknowledging receipt of this amendment on each copy of the offer submitted; or
3. By separate letter, telegram, or Electronic Mail which includes a reference to the solicitation and amendment numbers.

**FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.**

RFP NIH-NIAMS-02-03 is hereby amended as follows:

Part I, The Schedule, Section C, DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK, ARTICLE C.1., Paragraph D, Statement of Work, subparagraph 3.c., Note to Offerors, is hereby amended to read as follows:

***[NOTE TO OFFERORS: The offeror should show expertise in the indicated areas for the assessment of pain and function associated with osteoarthritis. The offeror is invited to suggest additional assessment measures for more complete evaluation of burden of disease. The offeror should provide evidence of capabilities to provide needed radiological services for subject x-ray evaluation with existing equipment within a time frame consistent with proposed recruitment. The offeror may choose to subcontract out for x-ray services. The offeror should provide a plan for purchase of dedicated MR imaging equipment. The offeror should propose means to meet MR imaging needs including appropriate space and budgetary requirements (e.g., costs for renovation, space rental, equipment purchase, and maintenance). The offeror is encouraged to propose alternative approaches to MR imaging capability including working with the Government to obtain mobile units, lease vs. purchase of dedicated MR units, etc.***

In addition, we have received several questions regarding the solicitation over the last few weeks. In order to allow us adequate time to answer future questions prior to the due date set for proposal submission, we hereby set a deadline for submission of questions by no later than **12:00 p.m., local time, October 15, 2001**. All questions must be submitted in writing to the Contracting Officer by the aforementioned date and time.

The following questions have arisen regarding this solicitation. Responses to the questions are provided below:

**Question 1.** Is a letter of intent required to submit a proposal, and if so when is it due?

**Answer 1.** Yes, we would like you to submit a Proposal Intent Response Sheet (Attachment 15). We did not set a deadline but will do so with this amendment #1. The deadline for Proposal Intent Notices is **October 22, 2001**.

**Question 2.** Will the Clinical Centers enroll clinic patients with osteoarthritis?

**Answer 2.** The OAI is intended to recruit a community based, rather than a clinic based population. This is NOT a clinical trial and does not include any treatment protocols. It is stated in the RFP that Clinical Centers will be expected to recruit individuals in the age range of 50-80 who are at "high risk" for OA. The sample inclusion criteria listed are obesity, previous knee injury, and low grade knee pain. These are examples, only. Exclusion criteria have not yet been defined. The goal is to enroll some individuals with no symptomatic knee osteoarthritis and some with early to mid-stage disease (mild symptoms) in order to capture clinical data associated

with knee osteoarthritis onset as well as early progression. This is a challenging goal. After the issuance of the contracts, the OAI Steering Committee will address the most appropriate inclusion and exclusion criteria to be implemented in the actual Manual of Operation Procedures.

**Question 3.** The Estimate of Effort listed in Section L.1., Paragraph F. of the RFP does not appear to be adequate for a clinical center. What should an offeror consider in responding to this RFP?

**Answer 3.** The Estimate of Effort is just that, an estimate. We indicate that this information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes. Offerors may not necessarily agree with how we foresee the staffing of the clinic. However, you should be aware that this is the basis upon which we established funding for this project.

**Question 4.** Are foreign organizations restricted from submitting proposals for this project?

**Answer 4.** Foreign organizations are not prohibited from submitting proposals in response to this solicitation. Section M of the RFP, paragraph 1, General, states that "If a proposal is received from a foreign organization or involves a foreign component, the peer review group will address the need or appropriateness of accomplishing the work outside the United States."